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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,069	04/11/2005	Yohko Akiyama	08279.1209USWO	2373

52835 7590 05/09/2008

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EXAMINER	
ELLIS, SUEZU Y	
ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
05/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,069	AKIYAMA ET AL.	
	Examiner	Art Unit	
	Suezu Ellis	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) *1-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/11/05, 7/3/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group III invention (claims 41-49) in the reply filed on March 24, 2008 is acknowledged.

Claims 1-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on March 24, 2008.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

The specification provides support for a pharmaceutical composition in the form of a tablet, granule or fine granules OR a capsule (pg. 14, lines 15-25), however does not appear to support the combination of a capsule having these ingredients.

Claim Objections

Claims 41, 42, 46 and 47 are objected to because of the following informalities:

With respect to claim 41, claim language recites "thereby an active ingredient being released in the pH range of no less than 5.5, nor more than 6.0". It appears claim

language should read "the active ingredient" for proper antecedent basis. Further, it appears "nor more" should be "no more".

With respect to claims 42, 46 and 47, claim language recites "an active ingredient". It appears claim language should read "the active ingredient" for proper antecedent basis.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 41-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 41 recites a capsule comprising a tablet, granule or fine granule. The specification provides support for a pharmaceutical composition in the form of a tablet, granule or fine granules OR capsule (pg. 14, lines 15-25), however does not appear to support the combination of a capsule having these ingredients.

Claims 42-49 are considered non-enabling due to their dependency.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 41-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 41, claim language recites "A capsule comprising (i) a tablet, granule or fine granule in which the release of active ingredient is controlled, said tablet, granule or fine granule comprises a core particle containing an imidazole compound (as an active ingredient)…, and a pH-dependently soluble release-controlled coating-layer and (ii) a tablet, granule or fine granule comprising a core particle containing an active ingredient and enteric coat." It is unclear if the tablet, granule or fine granule of (ii) is different than that of (i), since both (i) and (ii) recite "an active ingredient". It is unclear if the active ingredients in (i) and (ii) different, therefore, it is unclear if there are two different tablets/granules in the capsule. If they are the same, claim language needs proper antecedent basis. Further, it is unclear if (a) some of the tablets/granules in the capsule are coated with the pH-dependently soluble release-controlled coating-layer (i) and the remaining tablets/granules are coated with the enteric coating (ii), or (b) if the pH-dependently soluble release-controlled coating-layer is the same as the enteric coating, thereby there being only one coating layer on the core particles or (c) if the core particle has an active agent, a pH-dependently soluble release-controlled coating-layer, **and** an enteric coating. Please clarify. Further, it is

unclear how a capsule comprises tablet(s), as recited in claim 41, since usually the pharmaceutical dosage form is either a capsule or a tablet, but not both. Please clarify.

With respect to claims 42 and 46, claim language recites "the core particle containing an active ingredient". It is unclear which core particle containing the active ingredient applicant is referring to since claim language in claim 41 recites two core particle, (i) and (ii), having active ingredients. Please clarify.

With respect to claims 43-45, claim language recites "the active ingredient". It is unclear which active ingredient applicant is referring to - the active ingredient in the tablet/granules of (i) or those of (ii)? Please clarify.

In short, the capsule seems to have two cores, multiple coatings of unknown locations due to antecedent basis problems, and no reference as to how the capsule is put together. Perhaps applicant should specify that there is a first core particle and a second core particle, if that is what is intended. The claims seem to be a literal translation from the foreign document and need a lot of re-writing.

Claims not specifically addressed are indefinite due to their dependency.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 41 and 43-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beckert et al. (WO 02/060415) in view of the teachings of Kelm et al. (US 5,656,290). Hereinafter, US 2003/0152627 will be referred to as an English equivalent translation.

With respect to claim 41, 43 and 47, Beckert et al. discloses a capsule comprising granules (pellets) having core particles containing lansoprazole (page 4, column 1, lines 12-13) and a pH-dependently soluble release-controlled coating-layer made of methyl methacrylate-methacrylic acid copolymer where the polymeric substance is soluble at a pH of 6.8 [0018], [0046] [0049], [0053], and granules (pellets) comprising core particles containing lansoprazole and an enteric coating that is dissolved, thereby releasing the active ingredient in the pH range above about 5.5 [0019], [0035]. Beckert et al. fails to expressly disclose the exact pH range being between 5.5 and 6.0. Kelm et al. teaches it is well known in the art that the pH is different in various parts of the gastrointestinal system and to utilize different coatings depending on the location of the active ingredient to be released (col. 10, lines 6-16, 47-60). Therefore it would have been obvious to one of ordinary skill in the art to adjust the pH range depending on the location of the drug to be released. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

With respect to claims 44 and 45, the modified Beckert et al. discloses the active ingredient (lansoprazole) can be optically active isomers and racemates or mixtures of diastereoisomers [0054].

With respect to claim 46, the modified Beckert et al. discloses the inclusion of a stabilizer [0104], however fails to expressly disclose the stabilizers being a basic inorganic salt. However, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

With respect to claim 48, the modified Beckert et al. discloses the pH-dependently soluble release-controlled coating-layer contains a mixture of two or more kinds of methyl methacrylate-methacrylic copolymers that have different release properties [0038], [0047]-[0050].

Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over in view of Beckert et al. in view of the teachings of Kelm et al. and further in view of Karehill et al. (WO 99/32091).

With respect to claim 42, the modified Beckert et al. addresses all the limitations of claim 41, however fails to expressly disclose the pH-dependently soluble release-controlled coating-layer formed on an intermediate layer that is formed on the core particle. Karehill et al. discloses a tablet or pellets comprising a separating layer (intermediate layer) formed on a core particle containing an active ingredient (pg. 6, lines 1-6). It would have been obvious to one of ordinary skill in the art to include an

intermediate layer in order to improve the chemical stability of the active ingredient and/or the properties of the dosage form (pg. 17, lines 15-18).

Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over in view of Beckert et al. in view of the teachings of Kelm et al. and further in view of Yamamoto et al. (US 5,264,223)

With respect to claim 49, the modified Beckert et al. addresses all the limitations of claim 41, however fails to expressly disclose the inclusion of a gel-forming polymer. Yamamoto et al. discloses a hard capsule comprising a gel-forming polymer (abstract). It would have been obvious to one of ordinary skill in the art to utilize a gel-forming polymer in order to provide a hard capsule with increased prevention of capsule film cracking for the predictable result of prevention of the deterioration of active ingredients within the capsule (col. 2, lines 25-34).

Telephone/Fax Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suezu Ellis whose telephone number is (571) 272-2868. The examiner can normally be reached on 8:30am-5pm (Monday-Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharon Kennedy can be reached on (571) 272-4948. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SE

/Sharon E. Kennedy/
Primary Examiner, Art Unit 1615